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3.0 510(K) SUMMARY

OCT 23 2012

Submission Date: July 27, 2012

Submitter Information

Company Name: CyDen, Ltd.
Company Address: Technium 2, Kings Road, Swansea, Wales, UK SA1 8PH

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Device Information

Trade Name: iPulse SmoothSkin Hair Removal System

Common Name: Light based over the counter hair removal system

Classification Name: Laser surgical instrument for use in general and plastic surgery and dermatology

Device Class: 21 CFR 878.4810

Predicate Devices: Shaser IPL Hair Removal System
Shaser Inc, K103560

Flash 'N Go
Home Skinovations Inc, K082298

Device Description: The iPulse SmoothSkin Hair Removal System is an intense pulsed light (IPL) system composed of a base unit housing the electrical and electronic sub-assembly and an umbilical cord which is connected to the applicator, located in which is the source of optical radiation, namely a Xenon flashlamp. The system is powered from AC power via an external power converter.

Intended Use: The iPulse SmoothSkin Hair Removal System is an over the counter device intended for the removal of unwanted hair.

Indications for Use: The iPulse SmoothSkin Hair Removal System is indicated for the removal of unwanted hair.

Performance Data: Nonclinical, clinical and usability testing has been completed on the iPulse SmoothSkin Hair Removal System. Nonclinical testing included biocompatibility, electrical safety and software testing. Clinical testing was conducted in 29 subjects. Each subject underwent three weekly treatments with SmoothSkin, with follow up reviews at four weeks and six months after the last treatment. The majority of study

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subjects (83.3%) experienced hair reduction, with a mean hair count reduction of 54.7% at six months. Usability testing was completed in 47 subjects to evaluate device human factors and label comprehension.

Comparison to Predicate Device: The iPulse SmoothSkin Hair Removal System has the same intended use, mode of action and similar operational characteristics as the predicate devices. Any minor differences between the iPulse Smoothskin Hair Removal System and the listed predicate devices do not raise any issues of safety or efficacy. Performance data supports that the device is as safe and as effective as the predicate devices for its intended use. Therefore, the iPulse SmoothSkin Hair Removal System may be found substantially equivalent to its predicate devices. A technical comparison to the predicates is provided below.

	PREDICATE DEVICES		**DEVICE**
Device Name	Flash N' Go	Shaser IPL	iPulse SmoothSkin Hair Removal System
Manufacturer	Home Skinovations ltd	Shaser Inc	CyDen Limited
Energy Medium	Xenon Arc Flashlamp	Xenon Arc Flashlamp	Xenon Arc Flashlamp
Wavelength Range	475-1200nm	650nm – 1100nm	530 – 1100nm
Pulse Duration	5 milliseconds	30milliseconds	Setting I: Single pulse 25milliseconds. Setting II: Double pulse 15ms on, 10 ms off. Setting III: Double pulse 10 ms on, 40 ms off.
Energy Density	$5J/cm^2$	$9J/cm^2$	$7\text{-}10J/cm^2$
Spot Size	$6cm^2$ (3cm by 2 cm)	$2cm^2$ (1cm by 2cm)	$3cm^2$ (1.3cm by 2.4 cm)
Delivery Device	Direct Illumination To Tissue	Direct Illumination to Tissue	Direct Illumination To Tissue
Pulsing Control	Finger Switch	Finger Switch	Finger switch
Skin Tone Sensor	Optical Measurement Integral to Handpiece Sensor moveable to treatment site	Optical Measurement Integral to Base Unit Sensor fixed in base unit, treatment site moved to sensor	Optical Measurement Removable from Base Unit Sensor moveable to treatment site
Specific Indications for Use	The Flash N'Go is an Over-the-counter device intended for the removal of unwanted hair.	The Shaser IPL is an Over-the-counter device intended for the removal of unwanted hair.	The iPulse SmoothSkin Hair Removal System is indicated for the removal of unwanted hair.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Cyden, Limited
% Becker and Associates Consulting, Incorporated
Mr. Austin Speier
Managing Director
2001 Pennsylvania Avenue, Suite 950
Washington, District of Columbia 20006

OCT 23 2012

Re: K122280
Trade/Device Name: iPulse SmoothSkin Hair Removal System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: OHT
Dated: July 30, 2012
Received: July 31, 2012

Dear Mr. Speier:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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2.0 INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K122280

Device Name: iPulse SmoothSkin Hair Removal System

Indications for Use:

The iPulse SmoothSkin Hair Removal System is indicated for the removal of unwanted hair.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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